SUMMARY and CONCLUSIONS

University of the Pacific School of Dentistry Clinical Research Protocol WHOTI G-040

Effect of Frequent Daily Use for Four Weeks of a MICRODENT® - containing, Sorbitol-based, Chewing Gum in Reducing Dental Plaque Accumulation When Compared to a Placebo Gum and A No-Chewing Control Period: A Double Blind, Crossover Treatment Design

PURPOSE:

The purpose of this clinical trial is to compare in normal human subjects the effect on dental plaque accumulation, with normal brushing, of multiple daily uses of a sorbitol-based, sugar-free MICRODENT®-containing chewing gum *versus* a placebo chewing gum without the active ingredient (Microdent®[1], is a proprietary melt-emulsion of dimethicone in a suitable poloxamer[2] which acts as an agent to both clean and modify the surface free energy of teeth) . It is an additional purpose to compare plaque accumulation during the use of both the test gum and the placebo gum by the same subjects with an equivalent period wherein no gum is chewed by those same subjects.

PROTOCOL:

Twenty healthy subjects with no oral disease and normal toothbrushing skills were instructed to use either a test gum containing MICRODENT®, a placebo gum or a commercial breathmint in a series of three, one-month test periods. During the gum test periods, one half of the subjects were assigned each product, then crossed over the following gum test period. Use of product was three times a day after meals. Normal toothbrushing habits were followed.

The plaque was stained just before the baseline examination and each of the three product use period final examinations. Examinations were scored utilizing an expanded Turesky Modification of the Quigley-Hein Method (Shaver-Schiff). Subjects were instructed to refrain from brushing their teeth on the morning of each examination so that the measurement represented a uniform 12 hour accumulation since last brushing. Subjects were given a rubber cup prophylaxis to reduce plaque to zero at the beginning of each product-use period.

ADVERSE EFFECTS:

No adverse effects on tooth surfaces or soft tissue were noted following any of the Experimental Chewing Gum or Control breath mints product-use periods.

CONCLUSIONS:

The Test Gum with MICRODENT® as the active ingredient (Gum Code 315) very significantly reduced the accumulation of plaque when compared to either the Placebo Gum (Gum Code 050) or the Mint Control or the Baseline. There was no significant difference between the Placebo Gum and the Baseline. There was no significant difference between the Control Mint and the Placebo Gum or the Baseline.

> *Overall, the Test Gum with MICRODENT® was **34 % more effective** in reducing the accumulation of plaque than the Placebo Gum when used three times a day for one month with regular brushing.*
>
> *Over all, the Test Gum with MICRODENT® was **35 % more effective** in reducing the accumulation of plaque than the No-Chewing Gum Control (Control Mint) when used three times a day for one month with regular brushing.*

To summarize the data across all trials:

	Whole Mouth Plaque Index Means	Percent Red'n Versus Placebo	Statistical Significance
Placebo Gum	2.248	---	---
Control Mint	2.282	+ 1.51	none
MICRODENT® Gum	1.485	- 33.94	p = <0.0001

Very statistically significant differences, at similar magnitudes of effect, were seen when the tooth surfaces were segregated into Proximal, Smooth and Posterior surfaces and analysed. The Complete Protocol is attached. Conclusions and Details are presented in the Tabulated Data Section, the Statistical Summaries Section and the Raw Data Section of the full report.

Of particular note is that the active ingredient in the chewing gum induced excellent plaque reduction on those surfaces where normal brushing habits are typically less effective, ie, the interproximal and posterier surfaces.

APPROVALS:

Dr. Thomas Schiff, D.M.D. — 8/12/98 — date
Principle Investigator

Ira D. Hill, Ph.D. — 8/11/98 — date
Sponsor's Representative

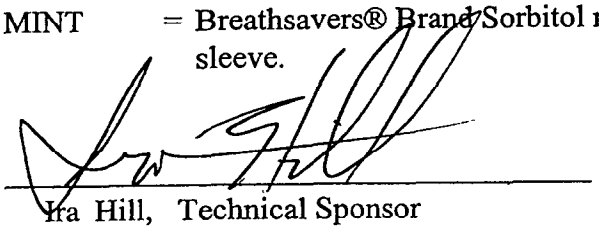
TECHNICAL SPONSOR'S "DE-CODE"

I hereby certify that the products submitted for evaluation under Protocol WHOTI G-040 are:

Product 050 = Placebo Gum with 0.0% MICRODENT®

Product 315 = Test Gum with 1.5% MICRODENT®

MINT = Breathsavers® Brand Sorbitol mints, commercially obtained and indentifying sleeve.



Ira Hill, Technical Sponsor